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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/182,102	10/27/1998	THOMAS HAAF	A-65680-2/RFT	1626

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EXAMINER
BRUSCA, JOHN S

ART UNIT	PAPER NUMBER
1631	31

DATE MAILED: 06/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

Office Action Summary	Application No.	Applicant(s)	
	09/182,102	WARD ET AL.	
	Examiner	Art Unit	
	John S. Brusca	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18,19,21 and 47-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18,19,21 and 47-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 28 May 2003 has been entered.

Drawings

2. The drawings are objected to because Figures 6A-6C are missing. Apparently the figures were filed with the original application at the time of filing, as indicated on the transmission paper of 27 October 1998. The missing drawings may have been lost by the Office. A copy of Figures 6A-6C are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18, 19, 21, and 47-53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

a) In order to practice the claimed invention one of skill in the art must identify a Rad51 mutation that is associated with a disease because the only asserted utility for the claimed invention is as a diagnostic for disease, as discussed in the specification on pages 9 and 15-16, and there is no other well recognized utility for the claimed invention. For the reasons discussed below, there would be an unpredictable amount of experimentation required to use the claimed invention.

b)No specific guidance is presented in the specification to identify a mutant Rad51 gene that is associated with a disease. The specification speculates on page 16, lines 3-6, that mutations in Rad51 genes might cause disease.

c) The specification does not present a working example of identifying a mutant Rad51 gene that is associated with a disease.

d) The invention is drawn to a method of identifying a Rad51 mutation that is associated with a disease

e) Vispe et al. was published before the filing date of the immediate parent Application No. 09/007020, and was received in the STIC library on 3/5/98. Vispe et al. reviews the prior art

concerning Rad51, and states that Rad51 is known to bind p53, BRCA1, and BRCA2 proteins. Vispe et al. does not show a disease caused by a mutation of Rad51. Vispe et al. states in the conclusion on page 590:

"Considering the role of Rad51 in recombination and potentially in cell proliferation, and its association with both BRCA1 and BRCA2, it is possible that mutations in either gene could increase genomic instability and/or disturb the cell cycle, leading to tumorigenesis. To support this hypothesis it would be interesting to look for RAD51 mutations in tumor cells."

Therefore, Vispe merely suggests that a screen to determine the possible existence of Rad51 mutations might be useful to study tumorigenesis.

f) The skill of those in the art of molecular biology is high.

g) The prior art does not predict that Rad51 mutations cause disease.

h) The claims are broad in that they are drawn to a method of identifying Rad51 mutations that are associated with disease although there is no guidance in the specification or the prior art as to what mutations of Rad51 meet the claimed limitations.

The skilled practitioner would first turn to the specification for guidance in performing the claimed method of identifying Rad51 mutations associated with disease. However, the specification does not disclose mutations of Rad51 that meet the claimed limitations, and so said practitioner would not be able to determine success or failure of the method. As such, the skilled practitioner would turn to the prior art for such guidance. However, the prior art does not teach the claimed method or Rad51 mutations that are associated with disease. Finally, said practitioner would turn to trial and error experimentation to perform the claimed method without guidance from the specification or the prior art. Such represents undue experimentation.

4. Applicant's arguments filed 28 May 2003 have been fully considered but they are not

persuasive. The applicants state that the claimed invention may be used for a utility other than a disease diagnostic. The applicants suggest other utilities that involve disease related to mutant Rad 51 genes. Such utilities are not enabled because any utilities related to a disease that correlates with mutations of Rad 51 genes is not enabled for reasons of record. The applicants point to Levy-Lehad et al. attached to their response filed 28 may 2003 as providing evidence that the claimed invention is enabled. However Levy-Lehad et al. was published on 13 March 2001, almost 4years after the instant effective filing date under 35 U.S.C. 119(e). Levy-Lehad et al. details specific mutations in Rad 51 that correlate with disease in human BRCA2 carriers. The details of the disease relationship shown in Levy-Lehad et al. were not described in the instant application **at the time of filing**, and so the instant application is not enabling for the embodiment of the claimed invention detailed in Levy-Lehad et al. The MPEP states in section 716.09:

> 716.09 Sufficiency of Disclosure
>
> See MPEP § 2164 - § 2164.08(c) for guidance in determining whether the specification provides an enabling disclosure in compliance with 35 U.S.C. 112, first paragraph. Once the examiner has established a prima facie case of lack of enablement, the burden falls on the applicant to present persuasive arguments, supported by suitable proofs where necessary, that one skilled in the art would have been able to make and use the claimed invention using the disclosure as a guide. In re Brandstadter, 484 F.2d 1395, 179 USPQ 286 (CCPA 1973). Evidence to supplement a specification which on its face appears deficient under 35 U.S.C. 112 must establish that the information which must be read into the specification to make it complete would have been known to those of ordinary skill in the art. In re Howarth, 654 F.2d 103, 210 USPQ 689 (CCPA 1981) (copies of patent specifications which had been opened for inspection in Rhodesia, Panama, and Luxembourg prior to the U.S. filing date of the applicant were not sufficient to overcome a rejection for lack of enablement under 35 U.S.C. 112, first paragraph). Affidavits or declarations presented to show that the disclosure of an application is sufficient to one skilled in the art

are not acceptable to establish facts which the specification itself should recite. In re Buchner, 929 F.2d 660, 18 USPQ2d 1331 (Fed. Cir. 1991) (Expert described how he would construct elements necessary to the claimed invention whose construction was not described in the application or the prior art; this was not sufficient to demonstrate that such construction was well-known to those of ordinary skill in the art.); In re Smyth, 189 F.2d 982, 90 USPQ 106 (CCPA 1951). Affidavits or declarations purporting to explain the disclosure or to interpret the disclosure of a pending application are usually not considered. In re Oppenauer, 143 F.2d 974, 62 USPQ 297 (CCPA 1944). But see Glaser v. Strickland, 220 USPQ 446 (Bd. Pat. Int. 1983) which reexamines the rationale on which In re Oppenauer was based in light of the Federal Rules of Evidence. The Board stated as a general proposition "Opinion testimony which merely purports to state that a claim or count, is disclosed' in an application involved in an interference . . . should not be given any weight. Opinion testimony which purports to state that a particular feature or limitation of a claim or count is disclosed in an application involved in an interference and which explains the underlying factual basis for the opinion may be helpful and can be admitted. The weight to which the latter testimony may be entitled must be evaluated strictly on a case-by-case basis."

Conclusion

5. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 703 308-4231. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703 308-4025. The fax phone numbers for the organization where this application or proceeding is assigned are 703 746-5137 for regular communications and 703 746-5137 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

John S. Brusca
Primary Examiner
Art Unit 1631

jsb
June 20, 2003